

SJ-EXHIBIT 10

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

MDL NO. 2804

CASE NO. 17-md-2804

Hon. Dan A. Polster

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

THIS DOCUMENT RELATES TO:

TRACK THREE CASES

VOLUME I

REMOTE VIDEO DEPOSITION OF

JAMES RAFALSKI

(CONTAINS TESTIMONY DESIGNATED HIGHLY CONFIDENTIAL)

June 10, 2021

REPORTED BY: Laura H. Nichols

Certified Realtime Reporter,

Registered Professional

Reporter and Notary Public

1 sections of the deposition that I should focus on
2 versus reading the entire deposition.

3 Q. Okay. Mr. Rafalski, it is kind of
4 early in your deposition to be violating the New
5 York court's instruction. Remember just answer --
6 if it is a yes or no question, please answer yes or
7 no so we can keep this thing moving as quickly as
8 possible.

9 MS. KNIGHT: That is totally
10 inappropriate. He is answering your questions. He
11 can explain his answers.

12 Q. (BY MR. LIVINGSTON:) Now, you have
13 no opinion at all in this case about the conduct of
14 any pharmacies in Lake and Trumbull Counties other
15 than the five defendant pharmacies in Track 3; is
16 that correct?

17 A. Yeah, that is a correct statement,
18 sir.

19 Q. And you have no opinion about whether
20 any of those pharmacies who you didn't examine or
21 offer any opinions about acted lawfully or
22 unlawfully with respect to their filling of opioid
23 prescriptions?

24 A. I believe that is a correct
25 statement. I am not offering an opinion on

1 Pharmacy for filling illegal -- filling
2 illegitimate opioid scripts?

3 A. I know there were some pharmacies
4 closed. I don't know the number, sir.

5 Q. Can you even identify for the record
6 a single pharmacy that was closed down by the Ohio
7 Board for illegally filling opioid scripts?

8 A. No, sir.

9 Q. And you also in your report offer no
10 opinions at all about whether the defendant's
11 pharmacy stores acted lawfully or unlawfully in any
12 way, shape or form with respect to the filling of
13 opioid prescriptions, correct?

14 A. Contained in my opinion, in my
15 report, I don't specifically cite any pharmacies
16 that were operating unlawfully, if that is your
17 question, sir.

18 Q. Maybe I am missing something, but
19 when I read your report, I only saw opinions
20 relating to the defendant pharmacies' distribution
21 activities, correct?

22 A. Yes, sir. That is an accurate
23 statement.

24 Q. Okay. There is nothing at all in
25 your report relating to the defendant pharmacies'

1 activities as pharmacies, i.e., filling
2 prescriptions?

3 A. That's a correct statement, sir.
4 There's nothing in my report on that matter.

5 Q. Now, you certainly have the
6 expertise, sir, to offer opinions about the
7 defendant pharmacies' operations at the pharmacy
8 level, correct?

9 MS. KNIGHT: Object to form.

10 A. I'm not sure that I have the
11 expertise of a pharmacist. I think with my
12 previous employment, I have done cases dealing with
13 pharmacies at a certain level. But the question
14 you asked was kind of broad.

15 So I don't have the ability to make
16 judgments on the actual filling of prescriptions.
17 It would be more of a pharmacist expert.

18 So potentially in certain aspects
19 maybe but not the way I think you have described it
20 or asked the question.

21 Q. (BY MR. LIVINGSTON:) Well, didn't
22 you investigate and shut down -- I will say bad
23 pharmacies in the Detroit area?

24 A. Yes, sir.

25 Q. And you have never been a

1 A. A diversion program manager, that is
2 a GS15.

3 Q. In those thirteen years, you did not
4 advance to group supervisor, is that correct?

5 A. No, sir. I had no desire to be in
6 management.

7 Q. When you applied to the DEA -- well,
8 before I ask that question, are you aware of the
9 fact that the DEA also has special agents?

10 A. Yes, I am aware of that.

11 Q. And unlike a diversion investigator,
12 a special agent has the ability to arrest people,
13 conduct surveillance, serve subpoenas and that sort
14 of thing and arrest people?

15 A. That would be a correct statement.
16 As a diversion investigator, I am not a law
17 enforcement officer, and the difference would be
18 that special agents are, so they carry guns, have
19 authority to make arrests, search warrants, handle
20 confidential informants, do surveillance. I am
21 restricted from doing those type of things.

22 Q. And over the course of your years
23 while you were with the DEA as a diversion
24 investigator, you would oftentimes work with
25 special agents when you were investigating a bad

1 A. I --

2 Q. You were asked about your geography
3 and you said, "In the Detroit office, I would cover
4 the lower peninsula of Michigan, the upper
5 peninsula of Michigan, and I would cover six
6 counties in Ohio, six northern east counties in
7 Ohio."

8 Toledo is northwest, correct?

9 A. Yes. Yes. Thinking about that
10 testimony, not -- not right when I said it, but as
11 you brought it up, and then thinking about the map
12 of Ohio and being aware that it goes quite farther
13 east than Michigan, it would be more correct to say
14 that the northwest -- northwest areas that border
15 Michigan.

16 Q. All right. Would you go to Page 7 of
17 your expert report, which is our Exhibit 2?

18 Do you see in the first full
19 paragraph at the top, you say, "As a DEA Diversion
20 Investigator with thirteen years of experience
21 (2004 - 2017), I am uniquely qualified to offer
22 expert opinions regarding compliance with federal
23 regulations governing the distribution of
24 controlled substances."

25 Do you see that statement?

1 A. I do.

2 Q. You're not telling the jury that
3 you're the only former or current DEA person who is
4 qualified to offer expert opinions regarding the
5 defendants' compliance with DEA regulations, are
6 you?

7 A. I don't think that statement implies
8 that, Mr. Livingston.

9 Q. Well, what did you mean by
10 "uniquely"?

11 A. Well, I've done a couple of
12 significant cases. The Masters case, the Harvard
13 case and the Mallinckrodt case, that all was
14 related to the distribution of oxycodone,
15 thirty-milligram products to Florida.

16 And as far as I'm aware, the
17 Mallinckrodt case was the first case that was ever
18 done regarding a manufacturer.

19 So I think there's some uniqueness to
20 my experience, but I don't mean that to mean that
21 there's not another person that can't testify or be
22 in the same capacity that I'm in.

23 Q. Yeah. I mean, the DEA has brought
24 hundreds of cases since you started, if not
25 thousands of cases, against pharmacies and

1 distributors throughout the United States since you
2 became a DEA employee in 2004, correct?

3 A. Well, I think that's accurate,
4 although not many of those cases went to an order
5 of show cause hearing and then rose through the
6 administrator's ruling and then to the federal
7 appellate court. I think that's one of the unique
8 things about my experience.

9 Q. Now, when you were at -- in order to
10 become a -- or when you became a DEA diversion
11 investigator, you had to go to a twelve-week
12 training course at Quantico in Virginia, correct?

13 A. That's correct, sir.

14 Q. And special agents also have to go to
15 Quantico to be taught about all of the regulations
16 that the DEA has and how to conduct themselves as a
17 special agent, correct?

18 A. That's a correct statement. I
19 believe it's longer than twelve weeks, though.

20 Q. Right. It's actually six months, as
21 opposed to three months, correct?

22 A. I don't know the exact number of
23 weeks, but it is longer, sir.

24 Q. Now, when you were with the DEA, you
25 performed what are called "preregistration

1 regulation?

2 A. That's not accurate.

3 Q. What other -- yeah. So let me
4 just -- so what other regulation, other than the
5 SOM regulation, do you claim that they did not
6 comply with?

7 A. Well, within the maintenance of
8 effective controls, it's -- I guess you
9 characterize it as -- it's an umbrella or an
10 overarching -- there's activities that registrants
11 conduct within -- specifically in a compliance
12 program would be due diligence. And the lack of
13 due diligence would be a failure that would lead to
14 the maintenance of -- the loss of the maintenance
15 of effective controls to prevent diversion.

16 It's not specifically in a
17 regulation, but it encompasses the activity to
18 ensure the holding of a registration.

19 Q. Okay. The due diligence requirement
20 that you speak of is not anywhere in any
21 regulation. But you believe that that obligation
22 does apply to the defendants with respect to the
23 operation of their SOM systems, correct?

24 A. It's not just the operation of their
25 SOMs. It's an activity they do to maintain their

1 effective controls to prevent diversion. I think
2 the ruling in the Masters case would confirm that,
3 in that that's what the Court held, is that due
4 diligence was an essential part of the compliance
5 with the regulation.

6 Q. All right. We'll get to those
7 regulations in a little more detail in a little
8 bit.

9 But during these investigations, both
10 preregistration and cyclic, one of the things that
11 you always make sure that you check is the SOM
12 system, if you're dealing with a distributor,
13 correct?

14 A. I would make sure that -- are we
15 speaking a new registrant?

16 Q. Well, I -- in both situations, you're
17 going to make sure that they either are going to
18 have a SOM system that complies with the DEA
19 regulations, or that they currently have and are
20 operating a SOM system that complies with the DEA
21 regulations.

22 A. Generally speaking, I agree with
23 that, yes, sir.

24 Q. I mean, that's right in the diversion
25 investigator manual, that you're supposed to check

1 MS. KNIGHT: That's exactly what I
2 said.

3 THE REPORTER: Thank you.

4 A. Mr. Livingston, I would say that I
5 would -- I would do preparations prior to going
6 on-site. But I am a little cautious about exactly
7 answering what I would do, what specific things I
8 would do prior to conducting an investigation.

9 Q. (BY MR. LIVINGSTON:) All right. And
10 was it DEA policy and practice, when you were with
11 the DEA, for DEA diversion inspectors to prepare a
12 report after they've completed their
13 preregistration and/or their cyclic inspection as
14 well, correct?

15 A. That's correct, sir.

16 Q. And those reports would at least be
17 available for the next inspection that the
18 registrant might have; is that correct?

19 A. Generally speaking, yes.

20 Q. And those reports were not given to
21 the registrant, right, after the inspection was
22 over? That was something that the DEA would just
23 keep in its files, correct?

24 A. I never provided one to a registrant.

25 Q. Okay. But you would have a

1 discussion with management, and you would let the
2 registrant know whether, in your view, they were in
3 compliance or not in compliance with all of the
4 applicable DEA regulations, correct?

5 A. There would definitely be a
6 management meeting. And depending on the outcome
7 of the investigation, would kind of dictate the
8 kinds of conversation.

9 I don't -- sometimes -- I would
10 generally be a little more cautious on being too
11 complimentary or too negative. It's kind of a pass
12 or fail.

13 Q. Okay. When you say "pass or fail,"
14 meaning they either were in compliance or they were
15 not in compliance, correct?

16 A. Sure. And if they were not in
17 compliance at the time of the management
18 conference, I didn't have the ability to tell them
19 what was going to occur based on my findings that
20 they were not in compliance.

21 So it wouldn't be a closed
22 conversation at the end because I -- sitting there,
23 I didn't have the ability to tell them. That's a
24 management decision.

25 Q. Okay. So if they weren't in

1 compliance, you wouldn't necessarily tell them
2 immediately. You would then go back to your
3 superiors at the DEA and discuss what next steps
4 might be?

5 A. That's a correct statement. As far
6 as in Detroit, that's how we did that.

7 Q. Okay. And, you know, in terms of DEA
8 enforcement efforts, when a registrant is not in
9 compliance with its regulations, what's the first
10 lowest level of enforcement that the DEA might
11 undertake?

12 A. Well, in some rare instances, there's
13 an actual on-site correction. So an example would
14 be some minor recordkeeping issue that can be
15 corrected on site, would be listed and would be
16 detailed, but not what -- it would be a corrective
17 action.

18 The next level up -- the next formal
19 level up, or the lowest formal level, would be a
20 letter of admonition.

21 Q. Okay. And then would the letter of
22 admonition essentially give the registrant a
23 certain period of time to try to get their act
24 together and get into compliance?

25 A. It generally gave them thirty days to

1 inspections had not identified any issue.

2 Q. (BY MR. LIVINGSTON:) And -- yeah,
3 I'm not talking about situations where, you know,
4 the registrant tells you, here's our system, but
5 they don't actually follow their system. They
6 don't actually operate it the way they tell you.

7 I'm just talking -- assuming that the
8 registrant actually operates the system in the
9 manner in which they've described it to you. And
10 you say, sounds good to me, shouldn't the
11 registrant -- and as a matter of all fairness -- be
12 able to rely on that representation that they're
13 fine?

14 MS. KNIGHT: Objection to form.

15 A. I don't fully disagree with what
16 you're saying. But I'd have to say that a
17 registrant is bound to comply with the regulations,
18 and that's not dependent on whether or not an
19 inspection is conducted, and an issue is not found
20 or discovered or detailed by a diversion
21 investigation, it doesn't relinquish the
22 responsibilities to comply with the regulations.

23 Q. (BY MR. LIVINGSTON:) Oh, no. Of
24 course, the law is the law. The question is
25 whether they can rely, in all fairness, on what

1 you're telling them as an expert. Right? These
2 are DEA regulations. You're a DEA investigator
3 whose job it is to enforce those regulations.
4 Nobody knows those regulations, presumably, when
5 you're on the job, any better than you, and you're
6 coming in to a registrant and you're telling them
7 that they're okay, shouldn't they be able to rely
8 on that?

9 MS. KNIGHT: Objection to form.

10 A. As I answered earlier, I generally
11 agree with that. But there are certain areas that
12 a registrant should -- would seek a higher
13 approval.

14 Q. (BY MR. LIVINGSTON:) Let's now --
15 I'd like to just give me a little road map here.
16 Let's now focus on the DEA regulations that you've
17 described in some detail so far this morning.

18 Let's -- to do that, let's --

19 MS. KNIGHT: Mr. Livingston, if we're
20 switching gears, can we just take a quick
21 five-minute comfort break? Is this --

22 MR. LIVINGSTON: Sure.

23 MS. KNIGHT: Okay. Real quick.

24 THE VIDEOGRAPHER: The time is now
25 approximately 9:18 a.m. We're off the record.

1 (Whereupon, a break was had from 9:18
2 a.m. until 9:32 a.m. EDT)

3 THE VIDEOGRAPHER: The time is now
4 approximately 9:32 a.m. We're on the record.

5 Q. (BY MR. LIVINGSTON:) Now,
6 Mr. Rafalski, when you were conducting cyclic
7 investigations of -- inspections of distributors
8 back in the day when you were a DEA diversion
9 inspector, you never had a Dr. McCann at your side
10 to use the ARCOS data to run the methodologies that
11 he ran on the registrant, correct?

12 A. No. I would have access to analysts
13 that worked in headquarters in ARCOS.

14 Q. And did you ever have them run all
15 these methodologies for a registrant?

16 A. No. You were -- I thought you were
17 speaking in terms of doing a regulatory
18 investigation.

19 Q. Yeah. I'm just asking that -- I know
20 that to test the Defendants' compliance in this
21 case, you used Dr. McCann to assist you in running
22 the data through your methodologies.

23 Did you ever do that, or something
24 similar to that, when you were a DEA diversion
25 inspector?

1 A. Yes.

2 Q. What did -- when did you do it and
3 with respect to whom?

4 A. I think that's going to be another
5 Touhy issue, Mr. Livingston.

6 Q. Well, you just said that you did it,
7 so I don't think it's a Touhy issue. We need to
8 know --

9 MS. KNIGHT: Mr. -- Mr. Livingston,
10 if he invokes Touhy, and believes that that's his
11 obligation under the law, then you can't override
12 that. You're very familiar with that rule.

13 MR. LIVINGSTON: I don't agree with
14 your position on it.

15 A. But I think to acknowledge it was
16 done is different than telling what I did or who I
17 did it with and who I did it for.

18 Q. (BY MR. LIVINGSTON:) Well, no. The
19 question was -- we know what you did because -- so
20 the question is: Did you ever take the seven
21 methodologies that are in your report and hand it
22 to somebody with a Ph.D. in data analysis to run
23 those methodologies through the registrant's data?

24 A. To that specific question, I would
25 answer no. I don't think that's the same question

1 you asked me earlier.

2 Q. So the answer is no?

3 A. That's correct. The answer is no.

4 Q. Okay. And remember when we were
5 talking before about the various levels of
6 enforcement that were available to you as a DEA
7 inspector, if a registrant was not in compliance
8 with the regulations? Do you remember when we
9 talked about that a minute ago?

10 A. Yes. Available to the agency, not to
11 me specifically. But, yes, I remember the
12 conversation.

13 Q. Right.

14 When you inspected distributors while
15 you were with the DEA, how often did you conclude
16 that they were in full compliance with all
17 applicable DEA regulations? Roughly, percentage,
18 you know, ten percent, sixty percent, a hundred
19 percent, ninety percent, whatever it is.

20 MS. KNIGHT: Objection to form.

21 A. Are you -- in regards to your
22 question, was that specific to distributors?

23 Q. (BY MR. LIVINGSTON:) Yes.

24 A. I think generally speaking, off the
25 top of my head, distributors -- there's a large

1 volume of regulations. So I would say that there
2 was generally at least maybe fifty percent, maybe a
3 little less of time where there would be some kind
4 of violation.

5 Q. Okay. All right. Would you turn to
6 Exhibit 6, Page 9? Giant Eagle Exhibit 6.

7 (GE Exhibit 6 was marked for
8 identification.)

9 Q. (BY MR. LIVINGSTON:) And the pages
10 are at the top. See, this is Section 1301.71 of
11 the DEA's Controlled Substance Act regulations?

12 MS. KNIGHT: Mr. Livingston, that's
13 not what's behind his tab.

14 A. 6? You said 6?

15 Q. (BY MR. LIVINGSTON:) Yes.

16 A. Tab 6 I have "Linden Barber" --

17 Q. Yeah. No. It -- yeah, but just go
18 to the Page 9 at the top. It's a compilation of
19 various -- yeah. Yeah. It was a trick question.
20 Sorry about that.

21 A. No. I didn't hear the "Page 9." I'm
22 sorry.

23 Okay. I'm there.

24 Q. Yeah. You're familiar with this
25 regulation, correct?

1 would mean in compliance, substantial, more than
2 just trying. It would be substantial in
3 compliance.

4 Q. Well, doesn't it mean less -- at
5 least less than one hundred percent?

6 A. That may be your interpretation. I
7 think "substantial" would mean in compliance.

8 Q. Well, are you saying that your
9 definition of "substantial" is there has to be
10 perfect compliance?

11 A. I don't know that I'm saying there's
12 perfect. But I think you couldn't find any obvious
13 faults. It would be in compliance.

14 Q. Well, I mean, let's just assume that
15 you're -- you get -- you're in compliance with nine
16 out of ten or ten out of eleven. I mean, is that
17 substantial? Or do you have to have perfect
18 compliance? You can't be noncompliant with any
19 regulation to be "in substantial compliance with
20 the regulations"?

21 MS. KNIGHT: Objection to form.

22 A. I think substantial -- because if we
23 look down at the column of different items to be in
24 compliance with, they're broad and they give
25 various descriptions. So I think "substantial

1 compliance" would mean you can't find any faults of
2 noncompliance.

3 I'm not sure I would say it has to be
4 perfect. But if you were to find that there were
5 an obvious failure to be in compliance, that would
6 not be substantial.

7 I think substantial is more than just
8 average or trying. I think it shows a high level
9 attempt to be in compliance.

10 Q. (BY MR. LIVINGSTON:) Now, you're
11 very familiar with the SOM regulation, correct?

12 A. Yes, sir.

13 Q. And that regulation says that you
14 have to have a Suspicious Order Monitoring system
15 that's going to identify orders of unusual size,
16 pattern or frequency, correct?

17 A. Well, in the beginning it says, "You
18 must design and operate."

19 Q. Yeah. But the system is supposed to
20 be able to identify unusual orders from a size,
21 pattern and frequency perspective, correct?

22 A. But I don't -- yeah, it does say
23 that, but I don't believe that's an exclusive
24 statement. That doesn't say that's the only things
25 that it should identify. But I would agree it does

1 you are saying, you are clarifying that Giant
2 Eagle's purported noncompliance only was from 2009
3 when they first started distributing Schedule 3
4 drugs, you say, through 2016?

5 THE REPORTER: You are getting a
6 little soft, Mr. Livingston.

7 MR. LIVINGSTON: Okay. Is that
8 better?

9 THE REPORTER: Yes, sir.

10 MR. LIVINGSTON: Thank you.

11 A. Well, they -- so there was two
12 facilities. The first facility stopped
13 distributing this 2014.

14 Q. (BY MR. LIVINGSTON:) Right. When
15 there was a reclassification from hydrocodone from
16 Schedule 3 to 2, correct?

17 A. Correct. And then they did not
18 self-distribute for a couple of years, and then
19 they started back self-distributing in 2016. So my
20 opinion definitely goes from 2009 to 2014 and then
21 when they started to self-distribute again from the
22 GERX DC, I have some information contained in my
23 report, but I did not have enough information to
24 make a definitive opinion on their conduct post
25 2016.

1 Q. All right. So let's just focus on
2 the gap period between 2014 and '16 when the second
3 facility known as GERX was opened up. You have no
4 opinion obviously that Giant Eagle was doing
5 anything wrong as a distributor because they were
6 not a distributor, correct?

7 A. No, I don't agree with that.

8 Q. So even though they were not a
9 distributor after 2014, you are saying they were
10 still not complying with the SOM regulation?

11 A. I didn't say the SOM regulation.
12 That wasn't -- I don't believe that was the
13 question you asked.

14 Q. Yeah, I think you are getting me -- I
15 am starting to chase my tail here or feel like it.

16 So are you saying yes or no that you
17 have an opinion post 2014 about Giant Eagle?

18 A. I believe the period between 2014 and
19 2016, there's a maintenance of effective controls
20 issue with the distribution from I believe it was
21 McKesson that distributed to them. But in
22 regards -- if we are just talking specifically
23 SOMs, I do not have an opinion past 2014 on the
24 SOMs issue.

25 Q. So in the period that you mentioned

1 opioids in those two counties, did you?

2 A. That's correct.

3 Q. You didn't look at any independent
4 pharmacies who were ultimately shut down for
5 writing illegal scripts in these two counties,
6 correct?

7 A. That's correct.

8 Q. You didn't look at what the amount of
9 theft from medicine cabinets or what have you after
10 scripts were filled in -- legitimate scripts were
11 filled in those two counties for opioids, correct;
12 you didn't try to figure that out?

13 A. That is correct, Mr. Livingston,
14 because I wasn't asked to form an opinion on those
15 things.

16 Q. And you weren't asked to look at what
17 contribution, if any, manufacturers of opioids made
18 by any conduct that they were responsible for,
19 including their marketing efforts, correct?

20 A. Not contained within this specific
21 opinion, that is correct.

22 Q. And in order to contribute to the
23 opioid epidemic in these two counties, the
24 defendant pharmacies had to have had problems at
25 the pharmacy level, correct?

1 MS. KNIGHT: Objection to form.

2 A. I do not disagree with that
3 statement.

4 Q. (BY MR. LIVINGSTON:) Right. I mean
5 just, this is, I think, pretty simple logic that
6 your focus was entirely on the defendants' conduct
7 as distributors, correct?

8 A. In concert with the distribution to
9 their pharmacies, yes.

10 Q. And even if the defendants were, you
11 know, as you claim, not doing a good job of
12 complying with DEA regulations at the distribution
13 level, if their pharmacies were exemplary
14 pharmacies with respect to controls against
15 diversion, and their pharmacies were doing
16 everything that a good pharmacy should be doing, at
17 the end of the day, there's -- it doesn't matter,
18 because there's not going to be any diversion as a
19 result of what the pharmacies were doing at the
20 distribution level, correct?

21 MS. KNIGHT: Object to the form.

22 A. Well, in that hypothetical, because
23 of the failures of the company, and not doing due
24 diligence and not providing me with the information
25 to see that that was actually accurate, there's no

1 perfect world, I don't think that your hypothetical
2 is possible. But in listening to your
3 hypothetical, if everything was absolutely perfect
4 with every pharmacy, then it is, hypothetically,
5 potentially it could be true.

6 Q. (BY MR. LIVINGSTON:) Now, when you
7 try to analyze whether a distributor is complaining
8 with the SOM regulation, you have to look at the
9 nature of the -- of the distributor's business,
10 correct? That is right in the regs, you are
11 supposed to take those sorts of things into
12 consideration?

13 A. Generally I agree with that, yes,
14 sir.

15 Q. And that is why the DEA -- you know,
16 there's no one-size-fits-all for SOM regulations,
17 correct?

18 A. I believe we touched on that earlier.
19 I believe that is why the regulation is good as it
20 stands, because it allows the ability for a
21 registrant to design their own system to meet their
22 own needs and their own customer base, and it is
23 fluid and allows them to change it. I don't think
24 there's a one-size-fits-all that could ever handle
25 the totality of distributor activities in there.

1 Q. Now, no matter how many times we look
2 at the DEA's some regulation, we won't find any of
3 the seven methodologies that you asked Mr. --
4 Dr. McCann to use when he crunched the data,
5 correct?

6 A. The DEA regulations never contained a
7 methodology or an algorithm.

8 Q. Okay. And, in fact, the DEA doesn't
9 even require that a registrant have an automated
10 threshold system. They can use a manual system if
11 they desire?

12 A. If they can -- if it can be designed
13 and operated and identify suspicious orders, yes,
14 sir.

15 Q. Okay. When you were inspecting
16 distributors, you know, while you were with the
17 DEA, did you ever recommend to any of them that
18 they use any of the methodologies that you are now
19 embracing in your report?

20 A. No, sir. It would have been improper
21 for me to do that. I think the farthest guidance,
22 probably the only guidance I can recall is there
23 was a period of time when the HDMA had a suspicious
24 order monitoring draft or a guide policy, and I
25 wouldn't direct a registrant to that, especially a

1 new registrant. But I may say that if they did
2 some Google research, they may get some good ideas
3 off the internet. But I never specifically
4 directed any registrant to any type of a suspicious
5 order monitoring system.

6 Q. Okay. Now, the results that
7 Dr. McCann came up varied greatly for each one of
8 the defendants under the methodologies that you
9 gave him to use, correct?

10 MS. KNIGHT: Object to form.

11 A. In your question, are you asking me
12 the results varied greatly?

13 Q. (BY MR. LIVINGSTON:) Yes, the
14 results.

15 A. Yes.

16 MR. LIVINGSTON: Let's go to
17 Exhibit -- Giant Eagle Exhibit 24.

18 (GE Exhibit 24 was marked for
19 identification.)

20 Q. (BY MR. LIVINGSTON:) This is a chart
21 that we had our version of a Dr. McCann put
22 together which is just really taking the results
23 from his report and your report for Giant Eagle.
24 This is a comparison of the methodologies for
25 flagging distribution orders, you know, seven

1 other things we have got to look at, but just
2 looking at this chart, this would suggest to you
3 that Giant Eagle's pharmacies are good pharmacies
4 that have proper controls and they are not engaged
5 in massive diversion, correct?

6 A. I couldn't draw that conclusion from
7 looking at this.

8 Q. Let me just -- you have examined or
9 you did examine when you were a DEA inspector many
10 pharmacies, correct?

11 A. I don't know that I would
12 characterize it many, but as part of my job I have
13 done that, yes, sir.

14 Q. Well, just for example, you examined
15 SafeScript, right?

16 A. That is correct.

17 Q. And that turned out to be a bad
18 pharmacy, correct?

19 A. That's correct.

20 Q. And when you investigate a
21 potentially a bad pharmacy, there are certain
22 things you look for, certain factors that you
23 consider to try to determine whether you have got a
24 good pharmacy or a bad pharmacy on your hands,
25 correct?

1 A. Yes. But I am not sure how you are
2 drawing a correlation to the chart. But when I
3 look at this chart, just for informational
4 purposes, I do see an escalation of the dispensing
5 of hydrocodone by the Giant Eagle pharmacies,
6 leading up to 2012 when many declines occurred
7 throughout the industry. So that would be a
8 concern, the years of 2009, '10, 11, exceeding the
9 quota, comparison quota. So that also would be
10 alarming to me or would be of concern to me.

11 Q. What factors would you look at --
12 look for to try to determine whether you have a
13 good pharmacy or a bad pharmacy?

14 A. I would look at ordering patterns and
15 I would look at -- I would review prescribing
16 patterns, prescriber patterns. That would be a
17 preliminary.

18 Q. What about, you know, Oxy A, that is
19 a high dose form of oxycodone --

20 MS. KNIGHT: Let him finish.

21 A. I wasn't quite finished, sir, I am
22 sorry.

23 I would look at the types of drugs
24 that were dispensed in relation to all drugs. I
25 would look at all drugs compared to controlled

1 substances. I would look at cash and noncash
2 payments. I would look at the volume. I would
3 look at the geographic area. I would look at other
4 pharmacies nearby. I would look at a bunch of
5 different factors in helping to draw a conclusion
6 on that issue we are talking about.

7 Q. (BY MR. LIVINGSTON:) Okay. And I
8 think -- I already know the answer, but you didn't
9 look at any of these factors with respect to any of
10 the pharmacies in this case, correct?

11 A. I wasn't asked to provide an opinion
12 on pharmacies, so I did not.

13 Q. Yeah. No, I don't care why you
14 didn't. I just want to know whether you did or you
15 didn't. You did not, correct?

16 A. I said I did not.

17 MS. KNIGHT: Asked and answered.

18 A. I was not asked to.

19 Q. (BY MR. LIVINGSTON:) Now, controls,
20 one of the things you suggested was your percentage
21 of controls versus noncontrols, correct?

22 A. That's correct, sir.

23 Q. And I think SafeScript, didn't they
24 have like ninety percent controls?

25 A. Yes. But I don't know the exact

1 versus noncontrols. And then as time went by, up
2 until 2012, it might get up as close as into the
3 twenties. And just based on the prescribing and
4 dispensing of controlled substances. And it
5 wouldn't just be opioids; it would be all controls.

6 But it would generally be around
7 twenty at the height. Unless there was some kind
8 of a reason that they were a specialty pharmacy,
9 they had contracts or special relationships that
10 were verified to be legitimate, that number could
11 be higher. We are just talking a general,
12 full-service pharmacy.

13 Q. Yeah. So I just want to make sure I
14 understand. You are saying that roughly around
15 twenty percent, if it was more than twenty percent,
16 you would start to get concerned about the level of
17 controls versus noncontrols?

18 A. I guess concern could be a good word.
19 It would be something that I might look at a little
20 closer, and that would be at the height.

21 Q. Well, what was the average level of
22 controls versus noncontrols? Was that something
23 that you knew when you were a DEA inspector?

24 A. Yeah, there would be published
25 reports or there would be information available or,

1 present, correct?

2 A. Yes.

3 Q. Okay. During that time frame, is
4 fifteen percent -- is that a reasonable number to
5 use for when you should start to get concerned
6 about whether there's diversion going on at a
7 pharmacy?

8 A. I don't think it is unreasonable.
9 Again, I'm just going to say unless there's some
10 kind of other reason for it to be above that level,
11 a justifiable reason.

12 Q. And then you also mentioned looking
13 at cash transactions, correct?

14 A. That would be another one of the
15 factors.

16 Q. What was the percentage, the usual
17 percentage that a good pharmacy would have of cash
18 transactions for controlled substances?

19 MS. KNIGHT: Objection to the form.

20 A. I think it -- and I'm not drawing a
21 direct -- I haven't really dealt with this topic
22 recently. I believe it would be low -- lower than
23 twenty percent. Just generally speaking.

24 Q. (BY MR. LIVINGSTON:) Okay. Fair
25 enough. Would you go to Exhibit, Giant Eagle

1 about?

2 MS. KNIGHT: Objection to the form.

3 A. Yeah. But I think in the totality of
4 my answer, I think that was one of the factors was
5 the percentage or within the percent of these. For
6 example, Newton Falls maybe could be all oxycodone
7 thirty milligram tablets. Just hypothetical.

8 (Reporter clarification.)

9 A. So I would agree, looking at the
10 percents, I don't see one here that is alarming,
11 but that is not definitively saying it is a good
12 pharmacy.

13 Q. (BY MR. LIVINGSTON:) Well, I think
14 our data consultants might have guessed where you
15 were going with your testimony. So let's go to
16 Exhibit 20, Giant Eagle Exhibit 20.

17 (GE Exhibit 20 was marked for
18 identification.)

19 Q. (BY MR. LIVINGSTON:) Do you see this
20 is a market share analysis of Giant Eagle's
21 opioids -- all opioids -- for all opioids at issue
22 in this case versus the Oxy 30s or greater. That
23 is what you just mentioned, right, the Oxy 30s;
24 that is a higher dose Oxy?

25 A. Yes. But just for clarification,

1 Q. All right. So essentially,
2 Mr. Crowley is asking you for some advice about
3 when he -- when he investigates a pharmacy, you
4 know, what he should look for as potentially signs
5 that, you know, there's a problem, correct?

6 A. Yes.

7 Q. And then you -- you provided him with
8 some guidance, correct?

9 A. Yes.

10 Q. And the first thing you say is you
11 would want to observe the pharmacy for a while.
12 You say, "I might also take some time and drive
13 around the surrounding area. Generally in Detroit
14 most of these problem pharmacies will have illegal
15 sales or transfer of pills from the purchaser to
16 someone outside. It is a fairly common activity."

17 I mean are you essentially saying you
18 want to be on the lookout for long lines of people
19 who are zombie-like or out-of-state licenses in the
20 parking lot of the pharmacy, that sort of thing?

21 A. Yeah, generally speaking. I don't
22 recall the names, but I recall the locations of a
23 couple of the pharmacies, and they were a
24 concerning area to go to in the city of Detroit.
25 So I am just giving him some general guidance about

1 what he might observe in the parking lots.

2 Q. And neither you nor Dr. McCann did
3 anything like that, neither of you ever went to any
4 of the pharmacies that are owned and operated by
5 the defendants in Lake and Trumbull Counties,
6 correct?

7 A. That is a correct statement, sir.

8 Q. And, to your knowledge, nobody --
9 none of the other experts or nobody, to your
10 knowledge, on plaintiffs' side did that, correct?

11 MS. KNIGHT: Object to form.

12 A. I do not know, sir.

13 Q. (BY MR. LIVINGSTON:) But to your
14 knowledge, you are not aware of anyone, correct?

15 MS. KNIGHT: Object to form.

16 A. As I stated, I don't know if anyone
17 did or did not do that.

18 Q. (BY MR. LIVINGSTON:) All right. The
19 next thing you list is "A good visual check of the
20 pharmacy says a lot. Pills, bottles, records
21 laying all around and disorganization is the norm
22 for most of the bad pharmacies." Do you see that?

23 A. Yes.

24 Q. And again, this is not something that
25 you and Dr. McCann or anyone else on the

1 case, if you were to make that inquiry, you would
2 be talking to the corporate office of these
3 pharmacies because they are all -- this is a
4 self-distribution situation where all the
5 pharmacies are owned by the same company, correct?

6 A. I am speaking about Mr. Crowley and
7 his visit to Detroit.

8 Q. Right, yeah. Purdue is a
9 manufacturer, so it is just a completely different
10 situation, right?

11 A. Well, it is a distribution from a
12 distributor to a pharmacy. It is not a chain, but
13 it is the same business. But I will agree with
14 you.

15 Q. Let's get to the more important
16 paragraph, the next one. It says, "You may already
17 know this, but a general pharmacy average for
18 ordering the eighty milligram" -- you are referring
19 to Oxy here, right, eighty milligram product?

20 A. Yes.

21 Q. -- "is approximately three hundred to
22 one thousand dosages units per month. If any
23 pharmacy you visit is ordering a larger amount and
24 not proportionate to the OxyContin strengths, then
25 you might want to investigate the totals more in

1 depth to ensure it is legitimate."

2 Do you see that?

3 A. Yes.

4 Q. So basically what you are telling
5 Mr. Crowley to be on the lookout for is, hey, if
6 you see that they are ordering, the pharmacy is
7 ordering more than a thousand doses, you know, it
8 is a red flag for you. And you might want to do
9 your due diligence to see if there really is
10 something amiss with the pharmacy, correct?

11 A. Conceptually, that would be a good
12 description of doing due diligence, by looking at
13 the distributions of strengths of drugs, I agree,
14 yes.

15 Q. Right. And conversely you are
16 telling Mr. Crowley that if the pharmacy has less
17 than a thousand dosage units per month, and
18 especially substantially less, then that shouldn't
19 raise his eyebrow, that would not be a red flag,
20 and he doesn't need to do any further due
21 diligence?

22 MS. KNIGHT: Object to form.

23 A. I don't think it would completely
24 preclude it, but generally speaking if it was much
25 less, a hundred couple dosage units a month, I

1 would tend to agree with that statement.

2 Q. (BY MR. LIVINGSTON:) Now I would
3 like you to turn to Exhibit 50.

4 (GE Exhibit 50 was marked for
5 identification.)

6 Q. (BY MR. LIVINGSTON:) And again, this
7 is something that our data consultants, using the
8 data that has been produced in this case, the OARRS
9 data, performed at our request. And this is
10 basically the average monthly oxycodone eighty
11 milligram dosage units dispensed by Overholts
12 Pharmacy. Do you know who Overholts Pharmacy is?

13 A. It's -- yes, generally speaking.

14 Q. Who is Overholts?

15 A. Well, it's an independent pharmacy.
16 I --

17 Q. And do you know what happened to
18 Overholts?

19 MS. KNIGHT: Mr. Livingston, you need
20 to let Mr. Rafalski finish his answer.

21 MR. LIVINGSTON: I'm sorry. I
22 thought he was finished. I'm just trying to move
23 it along.

24 MS. KNIGHT: Well, we've spent all
25 morning talking about areas that he doesn't have

1 dosage units dispensed. This is for Giant Eagle's
2 pharmacies in these two counties on a pharmacy by
3 pharmacy basis.

4 And do you see that for the most
5 part, most months for most pharmacies, literally
6 there was -- there was not one dosage of -- dose of
7 eighty milligram oxy that was dispensed and filled?
8 Do you see that?

9 A. I see that's what these charts show.

10 Q. And again, just looking at this, if I
11 just put this in front of you, said would this
12 cause you any concern, you know, about this
13 pharmacy, you would say no, this looks exemplary;
14 this looks like this pharmacy is hardly involved in
15 dispensing this drug at all, correct?

16 MS. KNIGHT: Object to form.

17 A. I don't know that I would use that
18 terminology, but if I saw those dispensing numbers
19 I obviously wouldn't rush to take a look at it, if
20 that was your question.

21 Q. (BY MR. LIVINGSTON:) That was the
22 question. Thank you for clarifying.

23 MS. KNIGHT: Mr. Livingston, when we
24 get to a good breaking point, let me know. It
25 would be great.

1 MR. LIVINGSTON: Okay. We're almost
2 there.

3 Q. (BY MR. LIVINGSTON:) Now, you did
4 make this comparison with respect to Safe Script.
5 You looked at Safe Script's oxy dispensing compared
6 to what other pharmacies were doing, correct? You
7 specifically looked at that?

8 A. Yes, sir.

9 Q. Okay. That's the exercise we just
10 went through. We looked at how much some of the
11 independents were dispensing, all defendants,
12 nondefendants, Giant Eagle, right, we just went
13 through that exercise?

14 MS. KNIGHT: Objection to form.

15 A. Yes, but again, it's just one
16 specific drug for a broad timeline. So it's a very
17 limited picture of the activity of the pharmacy.

18 Q. (BY MR. LIVINGSTON:) Did you review
19 any of the testimony in this case that was provided
20 under oath by several Ohio Board of Pharmacy agents
21 who were responsible for Lake and Trumbull
22 Counties, did you look at that testimony?

23 A. No, sir. I did not.

24 Q. So you're not aware of the fact that
25 Agent Pavlich testified under oath that

1 Dr. Franklin, who was ultimately -- well, he
2 ultimately was killed by his wife, but before that
3 happened, he got in trouble with the Ohio board for
4 dispensing, writing bad scripts for opioids.

5 You didn't know that Mr. Pavlich
6 testified that Dr. Franklin would write scripts for
7 opioids and he would tell his customers, do not
8 fill at the Giant Eagle and Rite Aids across the
9 street, go to Overholts; you're not aware of that
10 testimony, are you?

11 MS. KNIGHT: Objection to form.

12 A. As I stated, I had not read those
13 depositions.

14 Q. (BY MR. LIVINGSTON:) And isn't that
15 kind of information the sort of thing, the sort
16 of -- it would be a factor to you that would
17 suggest that those pharmacies were good pharmacies
18 and were not bad pharmacies with respect to the
19 diversion of opioids in these counties?

20 MS. KNIGHT: Objection to form.

21 A. I wouldn't draw that conclusion from
22 that.

23 Q. (BY MR. LIVINGSTON:) Well, would you
24 draw the conclusion that you should get on your
25 phone and call up the local police and say, you

1 better scope out Giant Eagle and Rite Aid? It
2 wouldn't cause you to do that, would it?

3 MS. KNIGHT: Objection to form.

4 A. That's totally outside of the
5 previous question. I just wouldn't come to make
6 that conclusion. It's such a limited amount of
7 facts why a doctor would say, don't fill them
8 across the street. Obviously maybe something
9 occurred and he directed them somewhere else, or he
10 already had a prearranged agreement with Overholts.

11 So just that broad statement, I can't
12 draw any conclusions from that.

13 Q. (BY MR. LIVINGSTON:) Are you aware
14 that the three agents all testified that all of the
15 defendants, to their knowledge and information,
16 were always in compliance with the Ohio Board of
17 Pharmacy regulations, including their many SOM
18 regulation and their corresponding duty
19 obligations, are you aware of that? Did you factor
20 that into your analysis?

21 A. I did not read their depositions and
22 I am not aware of that testimony.

23 Q. So the plaintiffs' attorneys did not
24 suggest to you that you should read those
25 depositions?

1 MS. KNIGHT: Object to form.

2 A. They don't suggest what to read or
3 what not to read. I -- I request documents to draw
4 my opinion.

5 My experience in dealings with boards
6 of pharmacies and the types of inspections they
7 conduct are more at a pharmacy level and typically
8 don't look at the same type of issues that I look
9 at.

10 Q. (BY MR. LIVINGSTON:) So are you
11 telling us that you didn't think it was important,
12 before you issued your opinion that these
13 pharmacies substantially contributed to the opioid
14 crisis in these two counties, it wasn't important
15 for you to look at what the Ohio Board of Pharmacy
16 agents had to say about whether those pharmacies
17 were acting lawfully or unlawfully?

18 MS. KNIGHT: Objection to form.

19 A. I don't qualify it as important or to
20 be unimportant. It is just something I didn't look
21 at in formulating my opinion.

22 Q. (BY MR. LIVINGSTON:) Well, we know
23 it wasn't important enough to be included on your
24 Schedule I, correct, as something that you
25 reviewed?

1 A. I did not review those documents,
2 sir.

3 MR. LIVINGSTON: I think we can take
4 a break.

5 MS. KNIGHT: Thank you.

6 THE VIDEOGRAPHER: The time is now
7 11:05 a.m. We're off the record.

8 MR. LIVINGSTON: Ten minutes.

9 (Whereupon, a break was had from
10 10:05 a.m. until 11:18 a.m. EDT)

11 THE VIDEOGRAPHER: The time is now
12 approximately 11:18 a.m. We're on the record.

13 MR. LIVINGSTON: I have still a
14 number of questions that I would like to ask this
15 witness. But as a matter of courtesy, I'm going to
16 now turn it over to my colleagues so that they can
17 get their questions in before the end of the day,
18 and then I will reserve my rights when they're
19 done, if there's time left, which I believe there
20 will be, to finish my questioning.

21

22 EXAMINATION BY MS. SWIFT:

23 Q. Mr. Rafalski, this is Kate Swift.
24 Can you hear me okay?

25 A. I can hear you, ma'am.

1 had an opportunity to look at, you can't say
2 whether Walgreens is one percent responsible for
3 the opioids crisis, ninety-nine percent responsible
4 or anything in between, correct?

5 A. I did not do an analysis that would
6 have quantified or given an amount of each
7 particular defendant in regards to their dispensing
8 or their activity. I didn't look at it that way.
9 It was just the two opinions that are in my report
10 are the only things that I focused on.

11 Q. You can't offer any assessment of the
12 level of responsibility that any of the five
13 pharmacies in the case have for any opioids crisis
14 in Lake or Trumbull County, correct?

15 MS. KNIGHT: Objection to form.

16 A. Well, what do you mean by level of
17 responsibility?

18 Q. (BY MS. SWIFT:) I mean what I was
19 asking you before, are you going to come in and say
20 Walgreens is one percent responsible for the
21 opioids crisis in Lake and Trumbull Counties? You
22 are not going to do that, right?

23 A. Well, I'm not going to put a percent
24 on there. I mean, my opinions are pretty well
25 stated in my report. It doesn't provide a percent

1 of conduct. It's just they failed it -- they
2 failed in the suspicious order monitoring system
3 and maintenance of effective controls.

4 So I have no intentions of coming in
5 and saying they're hypothetically thirty-three
6 percent responsible.

7 Q. Or any other level of responsibility?

8 A. Correct.

9 Q. Quantified?

10 A. Correct. It's just a failure as I
11 pointed out in my report.

12 Q. You're not connecting any failure
13 that you identify in your report to a level of
14 contribution to an opioids crisis in Lake or
15 Trumbull County, correct?

16 MS. KNIGHT: Object to form.

17 A. Well, I'm saying there's a
18 contribution. I am just not putting a figure on
19 it.

20 Q. (BY MS. SWIFT:) You can't quantify
21 the contribution; is that fair?

22 A. I did not try to do that, that's
23 correct.

24 Q. And you can't do it; is that fair?

25 MS. KNIGHT: Object to form.

1 pharmacists refusing to fill prescriptions from
2 suspicious and known intentional overprescribers."

3 Did I read that part correctly?

4 A. You did.

5 Q. It goes on to say, "It is also
6 recognized that direct dispensing by prescribers of
7 controlled substances is not submitted to the of
8 Ohio's prescription monitoring system, OARRS." Did
9 you know that there was ever a period of time where
10 dispensing of controlled substances directly by
11 doctors was not reported in the OARRS system? Was
12 that something you were aware of?

13 A. I was not.

14 Q. But you do know that sometimes
15 doctors dispense directly to patients, right, sir?

16 A. Practitioners have the ability to
17 dispense as long as they comply with some of the
18 regulations required. I know that in Michigan they
19 report, just I did not know at least in 2009 that
20 they did not report in Ohio.

21 Q. The next sentence reads, "In 2009,
22 Ohio prescribers dispensed prescription opioids at
23 a much higher rate than neighboring states." Did
24 you know that?

25 A. I did not.

1 Q. And then it refers to Figures 12 and
2 13, and you can see the figures there on the page,
3 right?

4 A. I can.

5 Q. Figure 12 shows that in 2009, Ohio
6 prescribers dispensed nine hundred and sixty-nine
7 thousand, three hundred and two dosage units of
8 oxycodone. Do you see that?

9 A. I do.

10 Q. And I am not going to take the time
11 to look at it, but if you look at this -- the
12 footnotes in this report on Page 75 of the PDF, you
13 can see that Footnotes 95 and '6 show that this
14 information comes from ARCOS data, and that is data
15 from the DEA, right, sir?

16 A. If it says it comes from ARCOS, that
17 would come from the DEA, that's correct.

18 Q. You recall that the document we were
19 looking at a moment ago, Dr. McCann's chart,
20 regarding the largest Walgreens in both Lake and
21 Trumbull County, the one on SOM Center Road, in
22 2009, that Walgreens received just three hundred
23 and twenty-five thousand doses of oxycodone. Do
24 you remember that?

25 A. I do.

1 were filled for either oxycodone or alprazolam."

2 Did you know that?

3 A. No, I did not know that specific
4 number.

5 Q. You didn't do any analysis of what
6 that number would be for any of the pharmacies,
7 stores in Lake and Trumbull County, correct, sir?

8 MS. KNIGHT: Objection to form.
9 Only -- Ms. Swift, I didn't hear your whole
10 question. I'm sorry.

11 Q. (BY MS. SWIFT:) You didn't conduct
12 any analysis of what that number would be, what the
13 percentage of prescriptions filled that were either
14 oxycodone or alprazolam, you didn't do that
15 analysis for any of the pharmacies in Lake and
16 Trumbull County, right, sir?

17 A. I did not.

18 Q. Paragraph 85 of the superseding
19 indictment says that, "The prescriptions filled at
20 American Pain reflect that approximately eighty
21 percent were for individuals who listed an address
22 outside of Florida." Were you aware of that?

23 A. I was not.

24 Q. All right. Do you have any idea how
25 many of those were for Ohio residents?

1 A. I do not.

2 Q. Paragraph 6 -- or, sorry, 86, tells
3 us -- you can see the last sentence says, "Patients
4 from Tennessee accounted for approximately 18.4
5 percent." Do you see that?

6 A. Do.

7 Q. And then it says, "Patients from Ohio
8 accounted for approximately 11.5 percent" of the
9 prescriptions we are talking about. Do you see
10 that?

11 A. I do. Now, is that -- is that -- and
12 this is specific for American Pain, correct?

13 Q. This is specific for American Pain.

14 A. Okay.

15 Q. You didn't conduct any analysis of
16 this pain clinic or any other in Florida for
17 purposes of your Lake and Trumbull report, right,
18 sir?

19 A. I did not.

20 Q. You haven't conducted any analysis of
21 any Florida pain clinic for any of your reports
22 that you have issued in the opioids litigation,
23 right, sir?

24 A. I have not provided an opinion or
25 done any analysis in Florida.

1 Q. You don't have any opinion about the
2 extent to which the doctors and pain clinics
3 described in this federal indictment contributed to
4 the opioids epidemic anywhere in America, correct,
5 sir?

6 A. Well, I have an opinion that they
7 contributed significantly, but I -- it would just
8 be through my experience of working in the DEA and
9 having knowledge of the migration of the pills.

10 But I didn't -- I did not offer an
11 opinion on that, yeah, an expert opinion on that,
12 I'm sorry.

13 Q. Do you know how many doctors wrote
14 prescriptions for opioids in Lake and Trumbull
15 County during the relevant time period, from 2006
16 to the present?

17 A. I do not.

18 Q. Do you know how many of those
19 prescriptions were illegitimate, meaning they
20 weren't for a legitimate medical purpose?

21 A. I do not.

22 Q. You don't have any opinion on how
23 many prescriptions filled by one of the pharmacies
24 in this case were diverted?

25 A. So a part of -- so in forming my

1 expert opinion, I wasn't asked to review any
2 materials, documents or information related to
3 that, so I don't offer an opinion on that.

4 Q. You have no idea if any prescriptions
5 filled by a Walgreens pharmacy were diverted; is
6 that fair, because you didn't look?

7 A. I did not review prescriptions for --
8 specific prescriptions at any Walgreens, so I guess
9 that would be generally a correct statement.

10 Q. Do you know how many prescriptions
11 filled by any of the other pharmacies in Lake and
12 Trumbull were diverted after they were filled?

13 A. I do not.

14 Q. That is true, whether we are talking
15 about somebody taking a prescription bottle from a
16 friend's medicine cabinet or any other form of
17 diversion, you don't have any idea what those
18 numbers are?

19 A. No. I wasn't asked to provide an
20 opinion on that, so I don't have any information to
21 form an opinion on that or to --

22 Q. And you are not --

23 A. -- or to provide you with any numbers
24 or any direct knowledge of that.

25 Q. You are not aware of any pills that

1 Walgreens shipped to one of its pharmacies that
2 went on to fill a prescription written by a doctor
3 who had prescribed that drug improperly, you
4 haven't done -- haven't done any analysis to match
5 that up; is that fair?

6 A. That is a fair statement. I have not
7 looked at the prescribing and matched it with some
8 of the doctors that were engaged in illicit
9 activity.

10 Q. Are you aware of any prescription
11 dispensed by a Walgreens or any of the other
12 pharmacies in this case where a licensed pharmacist
13 wasn't involved in the dispensing?

14 A. I haven't done a review to provide an
15 opinion on that, Ms. Swift.

16 Q. Are you aware, Mr. Rafalski, that the
17 DEA conducts routine investigations of distributors
18 every few years or so? I think actually you
19 testified a little bit about that earlier today; is
20 that right?

21 A. Cyclic or work-plan investigations
22 you are speaking of, that would be correct.

23 Q. And those routine investigations are
24 meant to insure compliance with the DEA's
25 regulations; is that fair?

1 A. That is -- yes, that is one of the
2 aspects.

3 Q. All right. You conducted
4 investigations like that when you were a diversion
5 investigator at DEA, right?

6 A. I did.

7 Q. I want to ask you a couple of
8 questions about some testimony from the DEA on how
9 the DEA conducts those investigations. But my
10 first question is, did you read the deposition
11 transcript of Claire Brennan in this case?

12 A. I did.

13 Q. Did you read the entire thing?

14 A. I did.

15 Q. You understand that Ms. Brennan is a
16 section chief in Diversion Control -- in the
17 Diversion Control Division of the DEA?

18 A. Yes, I am aware of that.

19 Q. All right. I am happy to show you
20 the testimony, but I am going to see if we can do
21 this quicker.

22 Would you agree with me that DEA
23 investigators can talk to whoever they want to at a
24 company to get their questions answered?

25 MS. KNIGHT: Objection to form.

1 Q. Yes.

2 A. No, I did not.

3 Q. Did you ever visit a pharmacy in Lake
4 or Trumbull County for purposes of preparing your
5 report?

6 A. I did not.

7 Q. And you never did the kind of
8 investigation you recommended to Mr. Crowley at
9 Purdue, correct?

10 A. That would be a much earlier time
11 frame, but, no, I did not go and sit and do any
12 observations at a Walgreens, that is a correct
13 statement.

14 Q. Or any other pharmacy in Lake or
15 Trumbull County, right, sir?

16 A. That's correct.

17 Q. You don't have any idea how many of
18 your flagged orders went to fill legitimate
19 prescriptions, right, sir?

20 A. Well, my flagged orders were flagged
21 for a specific reason. So it didn't make a
22 determination of what was diverted or what was not
23 diverted, but just my opinion is, based on the lack
24 of the due diligence on the first flagged order,
25 that more likely than not that those flagged orders

1 were diverted, but not specific to any specific
2 prescription.

3 Q. Sir, I would like you to listen to my
4 question. That wasn't my question at all.

5 My question was whether you have any
6 idea how many of the orders that you flagged in
7 your flagging analysis on the distribution side
8 went to fill legitimate prescriptions?

9 MS. KNIGHT: Asked and answered.

10 A. I don't have any specific knowledge
11 to answer that specific question, Ms. Swift.

12 Q. (BY MS. SWIFT:) You never made any
13 attempt to connect your flagged orders with any
14 specific prescription?

15 A. That is a correct statement. I did
16 not.

17 Q. All right.

18 MS. KNIGHT: Are we at a good
19 stopping place?

20 MS. SWIFT: I have got one more
21 question. I know that is a dangerous thing for a
22 lawyer to say.

23 MS. KNIGHT: Okay.

24 Q. (BY MS. SWIFT:) I will try to do
25 without pulling up the document to make it go

1 file would go and search all these other entities
2 to try to find any records related to due
3 diligence.

4 Q. Does the DEA define what needs to be
5 maintained in the customer file? Is that something
6 I can go look up in a code somewhere?

7 A. You cannot.

8 Q. In your report, you talk about
9 certain enforcement actions against Rite Aid,
10 against other entities and whatnot. Do you
11 remember having that in your report?

12 A. They are, enforcement actions are
13 here, yes, ma'am.

14 Q. Did you do any research to see if
15 there was a factual nexus between the alleged
16 conduct in the enforcement actions that you listed
17 and the allegations against the defendants in this
18 case?

19 A. I'm not sure I understand that
20 question.

21 Q. So let me ask it a little
22 differently. Did you go through and check that
23 each of the enforcement actions you listed, for
24 example, pertained to actual stores in the
25 jurisdictions in this case?

1 You agree that the Controlled
2 Substances Act and the regulations promulgated
3 under it do not prohibit registrants from relying
4 on employee experience to fulfill their regulatory
5 obligations, correct?

6 MS. KNIGHT: Asked and answered.

7 A. I don't think the regulation speaks
8 specifically to that. I believe earlier we were
9 discussing a manual system. That is what I was
10 responding to earlier.

11 Q. (BY MS. FUMERTON:) And a manual
12 system is not prohibited either, correct?

13 A. It is not what? I'm sorry.

14 Q. Prohibited, correct?

15 A. A manual system is not as long as it
16 is sufficient to meet the needs of the registrant.

17 Q. You also mentioned the twenty bottle
18 limit that Walmart instituted for oxy 30 in 2012;
19 do you recall that?

20 A. I do.

21 Q. Sorry. 2012. I said it right. Do
22 you know why Walmart implemented that policy?

23 A. Yeah, I recall seeing an email. It
24 was in response to concerns about diversion of
25 oxycodone 30 in West Virginia and Florida.

1 A. A little less but approximately, yes.

2 Q. Would you agree with me that a lot of
3 your opinions relating to CVS's SOMS system are
4 based on the absence of records or documentation?

5 MS. KNIGHT: Objection to form.

6 A. Specifically on the SOMS, I don't
7 totally agree with that. If it is in regards to
8 the maintenance of effective controls -- that would
9 be a more accurate answer or more accurate
10 question -- I would say I do.

11 Q. (BY MR. RUIZ:) Can you parse that
12 out for me? What do you mean?

13 A. Well, I think I have a good
14 understanding of the SOMS, how it is designed and
15 how it operated. So I don't think, in regards to
16 your question, my opinion is not because I don't
17 have sufficient information. I think the area
18 where I didn't see any sufficient information would
19 have been the due diligence that would have been
20 conducted in a more formal and systematic way.

21 Q. I understand. Okay. So you are
22 basing your opinion relating to due diligence on
23 the lack of documentary evidence today based on
24 events that occurred in 2010, 2011, 2012; is that
25 right?

1 A. Yes. So just for clarification,
2 documentary -- I am looking for a total -- a total
3 number of things, not just -- not just some pieces
4 of paper and documents. Policies, procedures, some
5 evidence that due diligence was conducted, how
6 pharmacies were open, all the due diligence that
7 would occur, not just related to a suspicious order
8 but in just conducting the business activity of a
9 distributor in a pharmacy -- with the pharmacy. I
10 am sorry.

11 Q. And my question is that you are
12 basing your opinion relating to that due diligence
13 based on the lack of evidence that you see in the
14 paper record on those points?

15 A. That is a correct statement, sir,
16 yes. I would agree generally with that.

17 Q. And you testified earlier that in
18 your opinion, distributors should retain records
19 related to their distribution of hydrocodone, even
20 after -- even years after they have stopped
21 distributing that product, correct?

22 A. Yes, I did state that earlier, and I
23 do believe that.

24 Q. So if a pharmacy has been open since
25 the 1980s, is it your opinion that CVS should have

1 kept documentation relating to orders that were
2 shipped more than thirty years ago?

3 A. I don't know if I would be as
4 definitive thirty years ago. But even records,
5 when they stopped distributing, which would be six
6 and a half or almost seven years ago, I still think
7 they should retain those records. Because I could
8 see a need where, you know, they are now conducting
9 business using Cardinal, where Cardinal may rely on
10 some of that activity prior to their distribution.

11 So I am not advocating they keep
12 records forever, but I think there's a
13 reasonableness to that also.

14 Q. What is the -- what is the cutoff for
15 you between six and thirty years? When can a
16 distributor get rid of records?

17 A. I think it would be more specific to
18 the type of due diligence. If it was something
19 severe, some kind of activity involving a pharmacy
20 and some employees and personnel, I think that
21 would be more significant in a longer time period.

22 If it was some due diligence that
23 was, say, for example, some people do site -- not
24 site visits, they do a monitoring where they sit
25 outside and watch for out-of-state license plates.

1 If one of those was thirty years old, I am not so
2 sure that would need to be retained.

3 But it would be up to the distributor
4 to, you know, provide those records that would show
5 what actions they took.

6 Q. What you just testified to there, has
7 that been provided in any DEA guidance to
8 registrants?

9 MS. KNIGHT: Objection to form.

10 A. That specific guidance, I am not
11 aware that it was ever provided by the DEA. I
12 think the only guidance that I was aware of is in
13 the distributor briefings. I attended two of them,
14 and the comment was made, "If it is not written
15 down, it didn't happen." That would be the exact
16 statement that they say at the distributor
17 briefing. And I am aware that also is not in the
18 law.

19 Q. (BY MR. RUIZ:) And you also don't
20 know whether or when CVS received a distributor
21 briefing, right?

22 A. I do not, sir.

23 Q. In your report, you discussed a 2013
24 DEA inspection of CVS's Indiana distribution
25 center. Do you recall that?

1 Q. So instead of saying "I have been
2 informed that a random spot-check," it should say
3 "I conducted a random spot-check," because you did
4 it yourself?

5 MS. KNIGHT: Object to the form.

6 A. I don't know that I would write it
7 like that. I think the documents could inform me.

8 But I think there was some
9 collaboration on this particular part of the
10 report.

11 Q. (BY MR. RUIZ:) Is that true for the
12 next sentence where you also write, "I have also
13 been informed"?

14 A. I believe so. I don't have a direct
15 recollection, but I believe so, sir.

16 Q. Let's turn to the next page, Page 78.
17 And at the bottom paragraph, the last sentence
18 says, "Additional investigation could include
19 review of patient profiles, such as the age,
20 distance traveled and method of payment, review of
21 ratios" -- do you see where I am reading?

22 A. No. I'm sorry. What page again?

23 Q. Page 78.

24 A. Oh, I'm sorry. Wrong page.

25 Q. And it is the last paragraph at the

1 bottom.

2 A. I see that.

3 Q. And it says there that "Additional
4 investigation could include review of," and then it
5 lists a number of things. Do you see that?

6 A. I do.

7 Q. Did you conduct any of these analyses
8 that you list here?

9 A. No, I did not. I put these in the
10 report because these are things that would be
11 readily available for CVS to do. It is not
12 something I did in writing my opinion, preparing my
13 opinion.

14 Q. Did you ask to review any of this
15 information for any CVS pharmacies in Lake or
16 Trumbull County?

17 A. I did not. And I -- and so, in
18 second to that, this would be some of the things
19 that I might expect to see in due diligence records
20 in regards to a review of materials for a pharmacy
21 for a suspicious order for other reasons, and I did
22 not see that. That is the other purpose for being
23 in the report.

24 Q. I didn't ask why you included it in
25 your report. My question is, did you ask to review

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION
4

5 MDL NO. 2804

6 CASE NO. 17-md-2804

7 Hon. Dan A. Polster
8

9 IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION
10

11 THIS DOCUMENT RELATES TO:

12 TRACK THREE CASES
13

14 VOLUME II
15

16 REMOTE VIDEO DEPOSITION OF

17 JAMES RAFALSKI

18 June 11, 2021
19
20
21

22 REPORTED BY: Laura H. Nichols

23 Certified Realtime Reporter,

24 Registered Professional

25 Reporter and Notary Public

1 deposition what the basis of this order being
2 blocked was, other than Giant Eagle's SOMS system?

3 MS. KNIGHT: Objection to form.

4 Q. (BY MR. LIVINGSTON:) Are you just
5 going to -- you're going to sit there and just
6 throw out some guesses for us?

7 MS. KNIGHT: Objection to form. And
8 that is an entirely inappropriate question.

9 MR. LIVINGSTON: No, it is not
10 inappropriate because it is clear --

11 Q. (BY MR. LIVINGSTON:) Do you have any
12 basis at all for telling the jury that this was not
13 blocked pursuant to Giant Eagle's existing SOMS
14 system back in 2014?

15 A. I will repeat my answer earlier. I
16 read the email and acknowledge it is being held by
17 the company. There's nothing in here that
18 definitively tells me it was blocked by the SOMS
19 system.

20 Q. Right. And there's nothing
21 definitively in here that tells you that it was not
22 blocked by the SOMS system, right?

23 A. That's correct.

24 Q. While we are on the topic of due
25 diligence in connection with your expert report,

1 one of the things that you did not investigate
2 before you rendered your opinion that somehow the
3 defendants contributed substantially to the opioid
4 crisis in Lake and Trumbull County was what impact,
5 if any, bad doctors had on the opioid crisis in
6 those two counties, correct?

7 A. Generally, that is correct, sir.

8 Q. And I won't replot old territory from
9 yesterday, but I think you did acknowledge that you
10 did not review any of the Ohio Board witness
11 deposition transcripts, correct?

12 A. That is a correct statement. That is
13 what I stated yesterday, sir.

14 Q. Would you go, turn to Exhibit --
15 Giant Eagle Exhibit 15?

16 (GE Exhibit 15 was marked for
17 identification.)

18 Q. (BY MR. LIVINGSTON:) And just the
19 first page, just to orient you -- and again, I know
20 that you didn't review this. You just
21 acknowledged --

22 A. One second, sir. One second.

23 (Pause.)

24 A. Okay. I am there.

25 Q. (BY MR. LIVINGSTON:) All right. You

1 But I didn't specifically investigate
2 Dr. Franklin's prescribing, if that is the question
3 you are asking.

4 Q. Okay. So previously I thought you
5 just told me this morning that you had not tried to
6 investigate to see what the impact of the bad
7 doctors writing bad scripts in Label and Trumbull
8 Counties were on the opioid crisis. But yet you
9 did do some research on these doctors? Is that
10 what you are telling us?

11 A. Only in to identify the existence of
12 some doctors that had been under investigation,
13 indicted or identified through a Google search.
14 That is correct.

15 Q. But for what purpose? Why were you
16 trying to identify them?

17 A. Predominantly, I was looking in the
18 areas of pharmacies that had high prescribing to
19 see if some of these doctors had offices specific
20 to those areas. Another one -- that would be the
21 general reason. And just that they existed.

22 There was -- I recall reviewing an
23 Attorney General press release that gave a
24 number -- a number of doctors and pharmacies that
25 had been -- lost their medical license. So I did

1 dispensing at the pharmacy level. I wasn't asked
2 to do an analysis of the pharmacies, so it wasn't
3 data that I requested. Because I did not need it
4 because I was not doing an opinion on that matter.

5 Q. (BY MR. LIVINGSTON:) All right.
6 Would you go to Page 187?

7 A. I am there.

8 Q. In the middle of that page, there's a
9 question asked. "And in your search warrant, on
10 the next paragraph you state that the review
11 confirmed that Dr. Franklin authorized fifteen
12 thousand two hundred ninety-eight controlled
13 substance prescriptions during the period of 4-10
14 of '06 through 6- 4 of '08, so a little more than
15 two years, these fifteen thousand controlled
16 substance prescriptions. Was that the time window
17 that you had narrowed your investigation down to?"

18 "Yes."

19 So Mr. Pavlich is telling us that
20 this one bad doctor alone during only a two-year
21 period -- remember, this case, the period for this
22 case goes from 2006 to the present. But this is
23 only two of those years, one bad doctor writing
24 fifteen thousand -- over fifteen thousand bad
25 scripts. And you didn't factor this into your

1 report, did you?

2 MS. KNIGHT: Objection to form.

3 A. I did not.

4 Q. (BY MR. LIVINGSTON:) You also didn't
5 factor into your analysis the effect that any
6 internet pharmacies had on the opioid crisis in
7 Lake and Trumbull County, correct?

8 A. That is correct.

9 Q. And that is despite the fact that you
10 knew from your time with the DEA that a major
11 contributor to the opioid crisis was internet
12 pharmacies, correct?

13 A. I am well aware of the effect of the
14 internet pharmacies. I don't know how it is
15 relevant to Lake and Trumbull County unless you are
16 indicating that maybe some of the residents there
17 were utilizing ordering those prescriptions online.
18 I'm not aware of any internet pharmacies that were
19 located in Lake and Trumbull County during the time
20 period of my review.

21 Q. Who said an internet pharmacy had to
22 be located physically in the county? Isn't that
23 the whole point, that you can just order on the
24 internet and have the drugs delivered to you?

25 A. That is the point.

1 have any discussions from any investigators in that
2 region of the country. All of my cases had links
3 to, as I stated earlier, Kentucky and Tennessee.

4 I was aware that there was some
5 bouncing back and forth across the state borders
6 because the maps or the PMP programs didn't link
7 between each state. But I'm not aware of any case
8 that was worked out of the Detroit office that was
9 specifically tied to those two counties.

10 Q. (BY MR. LIVINGSTON:) Well, one thing
11 for sure we know from reading your report is that
12 you did not take into consideration the impact that
13 drug gangs had on selling illegitimately obtained
14 opioid scripts in Lake and Trumbull County,
15 correct?

16 A. No. My report, Mr. Livingston,
17 focuses on the distribution from the distributor
18 down to the pharmacy. My analysis doesn't focus on
19 the illicit conduct outside of that action.

20 Q. Okay. And -- well, you also didn't
21 review any of the law enforcement depositions that
22 were taken in this case in which testimony was
23 given that Detroit was a major supplier of
24 illegally obtained opioid pills to Lake and
25 Trumbull County, correct?

1 MS. KNIGHT: Object to the form.

2 A. I didn't review those reports. I
3 would be interested to look at one if you have one
4 available or in the binder.

5 Q. (BY MR. LIVINGSTON:) You -- I don't
6 want to leave you in anticipation. Let's go to
7 Exhibit -- Giant Eagle Exhibit 25.

8 (GE Exhibit 25 was marked for
9 identification.)

10 Q. (BY MR. LIVINGSTON:) This is --
11 Exhibit 25 is Ohio State Highway Patrol, Critical
12 Information and Communications Center, Criminal
13 Intelligence Unit, Issue Date -- and it has
14 "Awareness: Prescription Drug Interdiction." And
15 it is dated August 9, 2012. Do you see that?

16 A. I do.

17 Q. Okay. This is during the relevant
18 time frame upon which your opinion is based,
19 correct?

20 A. It is.

21 Q. Okay. Did you review this document
22 in connection with the preparation of your report?

23 A. I don't recall looking at this
24 specific document, sir.

25 Q. Okay. When you were a DEA agent,

1 that have occurred where they are published on the
2 Federal Register or on the DEA website in regards
3 to pharmacies and their corresponding
4 responsibility. So I think there's plenty of
5 information available.

6 Have they specifically sent a list
7 out of red flags? I'm not aware of that.

8 Q. You didn't do any analysis to
9 determine to what extent the defendant pharmacists
10 in Lake and Trumbull County properly discharged
11 their duty to exercise their corresponding
12 responsibility?

13 A. I did not.

14 Q. And you did not endeavor to try to
15 determine whether any suspicious order at the
16 distribution level with respect to any of the
17 defendant pharmacies ultimately was used to fill an
18 illegitimate or not legitimate prescription,
19 correct?

20 A. That was not part of my analysis, no,
21 sir.

22 Q. Turn to Exhibit 2, your report,
23 Schedule I.

24 MS. KNIGHT: So Mr. Livingston, I
25 believe that is the -- I don't know what was wrong

1 A. That's correct.

2 MS. KNIGHT: Objection to form.

3 Q. (BY MR. LIVINGSTON:) And unlike
4 Mr. Colosimo and the other folks at the DEA
5 Pittsburgh office who inspected Giant Eagle's
6 facilities, you never actually physically inspected
7 either HBC or GERX; is that correct?

8 A. I never was physically present at
9 either of those locations, sir.

10 Q. Did you ever ask plaintiffs' counsel
11 for that opportunity?

12 A. To go there and inspect them?

13 Q. Yes.

14 A. I did not.

15 Q. Did they ever tell you that that was
16 an option, that under the Federal Rules, a party
17 can request and obtain the right to physically
18 inspect the other parties' facilities?

19 A. They did not tell me that. I am not
20 aware of that, sir.

21 Q. Now that you are aware of it, is that
22 something that you wish you had had the opportunity
23 to do before you rendered your opinions in this
24 matter?

25 A. Well, I think anything that I could

1 do to further gain information would be -- not
2 critical but important. If I had a choice to do
3 anything, I wish I could interview the people
4 myself versus the deposition. That is what I would
5 wish to do first. But anything would be important,
6 sir.

7 If I could go onsite, I'm not sure I
8 could -- it would be relevant as far back as my
9 review is, but I wouldn't preclude doing anything
10 that would gain further information.

11 Q. Now, to try to set the scene a little
12 bit, were you aware that Giant Eagle, before it
13 opened up its H -- or obtained its license,
14 Schedule 3 license for HBC in 2009, that prior to
15 that, it had a List 1 chemical distribution
16 license?

17 A. I generally recall seeing something
18 about that in the document review, yes.

19 Q. And that in order to obtain that
20 license, there's similar requirements, not
21 necessarily identical but somewhat similar to the
22 requirements for -- a distribution license for
23 Schedule 3 drugs, correct?

24 MS. KNIGHT: Objection to form.

25 A. I think a List 1 chemical distributor

1 myself and thinking about that number and being a
2 guess, and I wasn't comfortable with it.

3 Q. All right. Did you ever have trouble
4 after you gave the New York testimony? Did you
5 ever recant that testimony?

6 A. I did not.

7 MS. KNIGHT: Objection to the form.

8 A. I did not.

9 Q. (BY MR. LIVINGSTON:) Well,
10 regardless of what the exact percentage is or is
11 not for how often the DEA would issue letters of
12 admonition after an inspection to a distributor,
13 you would agree that Giant Eagle's record of all
14 clean inspections for three preregistration
15 inspections and eight cyclic inspections is
16 exemplary, correct?

17 MS. KNIGHT: Objection to form.

18 A. I would say that is expected.

19 Q. (BY MR. LIVINGSTON:) Well, you said
20 it was expected, but you also have said that it
21 was -- forget the percentage, that it certainly
22 wasn't uncommon for even a single -- for
23 distributors to get letters of admonition for not
24 being in compliance after an inspection?

25 A. I did say that. And doing

1 never kept records to be able to accurately answer
2 that, and I don't want to guess.

3 Q. And did you ever find that a
4 distributor's SOMS system that you inspected was in
5 compliance?

6 A. I believe there were some, yes.

7 Q. Okay. And what kind of threshold
8 system did they have?

9 A. Without disclosing the registrant,
10 one that I recall, because I had concerns going in,
11 was a manual system. And I actually found that to
12 be compliant, but it was based on a business
13 activity and the abilities and knowledge of the
14 employees.

15 I can recall a couple of smaller
16 companies that had compliance systems. I can also
17 recall some that did not. But off the top of my
18 head, I didn't really keep records or I don't have
19 a recollection specifically of the different
20 companies and what they had and didn't have.

21 Q. Without disclosing the name of the
22 registrant, the one that was a manual system, can
23 you tell us what was the nature of the business?
24 You said based on business activity. What did you
25 mean by that?

1 it off the top of my head.

2 Q. And how did the manual system work?
3 Was there just people who were fairly familiar with
4 the customers who would, you know, identify
5 unusually large orders or suspicious orders of some
6 sort?

7 A. There was a multitude of things they
8 did. There was more of an intimate relationship
9 with the sales. The CEO was in the field a lot and
10 sales. And they used -- actually used people to
11 evaluate some companies. They had questioned some
12 outside consultants. The compliance people had
13 pretty intimate knowledge of who their customers
14 were and what they were ordering.

15 During my interview, I didn't find
16 any areas where they weren't -- didn't have
17 knowledge of the customers that I reviewed or the
18 questions that I had.

19 Q. So one of the things that gave you
20 comfort was their familiarity that the compliance
21 people had with their customers?

22 A. Well, it was a multitude of things,
23 but that was one. You know, they had an
24 onboarding, they had customer files. They had a
25 knowledge of what they were ordering. They were

1 aware if there were increases. It was a system
2 that I didn't find any faults with on that
3 particular inspection. I don't know moving forward
4 if it changed, but --

5 Q. All right. So you are aware that
6 Giant Eagle never received a letter of admonition,
7 correct?

8 A. I believe that is an accurate
9 statement, yes, sir.

10 Q. There was never any kind of
11 administrative action of any kind ever taken
12 against Giant Eagle for violating any DEA
13 regulations, correct?

14 A. Not that I am aware of.

15 Q. And Giant Eagle never was penalized
16 or entered into any kind of memorandum of
17 understanding for any violation of any DEA
18 regulations, correct?

19 A. That's correct.

20 Q. And you at least know -- you would at
21 least acknowledge that Giant Eagle was found to be
22 in full compliance at the conclusion of every
23 inspection that I mentioned to you earlier?

24 MS. KNIGHT: Objection to form.

25 A. I'm not sure that I reviewed every

1 recordkeeping and security are in full compliance,
2 it is a pretty broad statement without looking at
3 the report.

4 Q. (BY MR. LIVINGSTON:) Yes.

5 A. Not that I need to read them all, but
6 I wouldn't disagree that the report may say that.
7 Maybe in summary at the beginning, I am guessing.

8 Q. And when you go -- and your opinion
9 that is in your report is that from 2009, when HBC
10 first was granted a license for Schedule 3 drugs,
11 until hydrocodone was reclassified in 2014, during
12 that entire period of time, Giant Eagle was not
13 even in substantial compliance; it wasn't in
14 compliance at all, right?

15 A. In regards to their SOMS system,
16 that's correct.

17 Q. In other words, you disagree with the
18 conclusions reached by all of these DEA agents,
19 correct?

20 MS. KNIGHT: Object to the form.

21 A. Well, that is why I would like to
22 review the documents to ensure that they even
23 inquired about those things in their investigation.
24 It is not a mandate that they be required. So I
25 would like to see what description they had and

1 what awareness they had of the system. But I am in
2 disagreement if it says full compliance with
3 security, I do not disagree -- I do not agree with
4 that statement.

5 Q. (BY MR. LIVINGSTON:) So you publish
6 your report in April, which contains all of your
7 final opinions for this case, and now we are taking
8 your deposition in June. And you haven't taken the
9 time to review any of these inspection reports,
10 correct?

11 MS. KNIGHT: Objection to the form.

12 A. That's correct.

13 Q. (BY MR. LIVINGSTON:) Well, I guess
14 now is as good a time as any to finally look at
15 these reports. Let's go to Exhibit 34.

16 (GE Exhibit 34 was marked for
17 identification.)

18 Q. (BY MR. LIVINGSTON:) Page, at the
19 top, we will go to Page 9.

20 MS. KNIGHT: Just a moment. Sorry,
21 Mr. Livingston. He is getting there.

22 A. Go ahead.

23 Q. (BY MR. LIVINGSTON:) Okay. You see
24 this is a report by Mr. Colosimo regarding the
25 approval of HBC's request for a Schedule 3 license

1 investigation has been concluded.

2 Q. Okay. And that means at that point
3 from the DEA's perspective, the registrant is in
4 compliance, correct?

5 A. No. It just means the matter is
6 closed.

7 Q. Why would you close the matter if the
8 registrant is still not in compliance? Wouldn't
9 you -- I mean that doesn't sound like the DEA would
10 be doing its job in that situation, right?

11 MS. KNIGHT: Objection to form.

12 A. Well, until -- if there's a pending
13 action with the registrant, it should remain open.
14 And that is the training. But I don't draw that
15 assumption. With some -- you know, in my career, I
16 know that some were closed prior to that conclusion
17 and they were supplemented. But generally speaking
18 when it says "case closed," the matter has had a
19 final resolution.

20 Q. (BY MR. LIVINGSTON:) Okay. Why
21 don't we skip down on to the third paragraph under
22 "Synopsis." And it says, "This investigation
23 revealed no discrepancies with respect to
24 security." That is just another way of saying
25 there was no finding of a violation of the DEA

1 thought it was, you know, important to know that
2 Giant Eagle wasn't a McKesson type distributor but
3 rather a self-distributor, correct?

4 MS. KNIGHT: Objection to form.

5 A. I don't know that's the purpose for
6 the comment. I think it is just part of preparing
7 a report, to give a base of information about the
8 registrant.

9 Q. (BY MR. LIVINGSTON:) But why include
10 that information if it is not important? Why would
11 you want to know whether they distribute to Giant
12 Eagle supermarkets or maybe Giant Eagle's HBC
13 supplying Rite Aid? I mean why wouldn't you -- why
14 would you note that if it is not important?

15 A. Well, I think it is important. But I
16 believe your statement was it was put on this
17 report to make a comparison to other larger
18 distributors. I think it is just a good
19 description of the registrant that is being
20 investigated. Maybe I misunderstood your earlier
21 statement.

22 Q. Okay. And let me just ask you,
23 typically, what percentage of a distributor like a
24 McKesson or, you know, I don't know,
25 AmerisourceBergen, Cardinal, what percentage of

1 diligence. I said they had good documentation of
2 due diligence. I don't know that a registrant
3 could be in full compliance and at the same time
4 get a corrective statement like that in the report.

5 I guess that may go back to the
6 earlier statement where they -- that I brought up
7 where they are going to notify management.

8 Q. And you know -- okay. Just to orient
9 ourselves, the date of this meeting with management
10 or this investigation and report is August of 2013,
11 correct?

12 A. That's correct.

13 Q. And isn't it true, sir, that in your
14 own report, you indicate that by the fall, late
15 fall of 2013, Giant Eagle had begun to use an
16 automated computerized threshold system to go along
17 with its manual SOMS system?

18 A. Yes, sir, mid October.

19 Q. Okay. So within two months, Giant
20 Eagle acted on this recommendation that they
21 received from Investigator Conlon, correct?

22 MS. KNIGHT: Object to the form.

23 A. I don't know that that was a reaction
24 to this. I didn't see a criticism of the manual
25 system, just a criticism of the due diligence.